

## ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
1. NHANES Respondents .....	3,850	1	2.4
2. Special study/pretest participants .....	2,037	1	2

Dated: August 30, 2012.

**Ron A. Otten,**

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Directors, Centers for Disease Control and Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**Medicare, Medicaid, and CHIP Programs: Research and Analysis on Impact of CMS Programs on the Indian Health Care System**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice of Single Source Award.

**SUMMARY:** This notice supports expansion of research on the impact of CMS programs on the Indian health care system through a single source award. The Indian Health Service (IHS), Tribes and Tribal Organizations and Urban programs, deliver health care services to American Indian/Alaska Native (AI/AN) people through a network of hospitals, clinics and other providers. This award expands research on the impact of CMS programs and the delivery of health care to AI/AN beneficiaries.

**FOR FURTHER INFORMATION CONTACT:** Rodger Goodacre, Centers for Medicare & Medicaid Services, Office of Public Affairs/Tribal Affairs Group, 7500 Security Boulevard, M/S S1-05-13, Baltimore, MD 21244-1850, (410) 786-3209.

*Intended Recipient:* National Indian Health Board (NIHB).

**Purpose of Award**

The IHS and Tribal health programs have had long standing authority to bill Medicare and Medicaid for services provided at their facilities. These participating and billing authorities were expanded by the American Recovery and Reinvestment Act of 2009 (ARRA), the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), and the Affordable

Care Act in 2010 (ACA). AI/AN people have traditionally been medically underserved and have health disparities significantly above those of the population as a whole. In order to ensure that AI/AN people have full knowledge of these new changes and the fullest access to CMS programs, this award will study the adoption and impact of these new authorities on the Indian health care system.

**Amount of the Award**

The total amount of funding available over a five year period is \$3,175,000.00. The initial award will be awarded at \$635,000.00. The subsequent years will be awarded on a non-competing continuation basis at approximately \$635,000.00 per year for 5 total years, and will be subject to the availability of funds and satisfactory performance by the recipient.

**Justification for Single Source Award**

For the past five years through Cooperative Agreements with IHS, NIHB has provided analysis and research of the potential and actual impact of CMS programs on AI/AN beneficiaries and the health care system serving these beneficiaries. This work has included extensive analysis and research on Medicare and Medicaid data enrollment of AI/AN beneficiaries to understand utilization of the AI/AN population in the context of CMS programs. In addition, the NIHB has been instrumental in tracking CMS regulations and providing analysis and research to better understand the implications of CMS regulatory guidance on the Indian health programs. Based on this experience, NIHB is the only entity capable of carrying out the scope of activities because the scope of work builds on past experience and knowledge. Any other source would not have all of the knowledge and experience gained in the last five years. The NIHB provides research on health program issues impacting AI/ANs to over 565 Federally-recognized Tribes and has historically provided these services for several decades in conjunction with the HIS. The NIHB program has a national focus relevant to its AI/AN constituency who need to

know through substantive research about the changes and updates in the latest health care services and access through CMS programs.

**Project Period**

The anticipated period of performance is for this cooperative agreement is August 31, 2012 through August 30, 2017 with funding awarded in 12-month budget increments subject to the availability of funds and satisfactory performance.

**Provisions of the Notice**

CMS has solicited a proposal from the NIHB to undertake analysis, research and studies to address the impact of CMS programs and AI/AN beneficiaries and the health care system serving those beneficiaries. The project consists of four principal research objectives:

- Study the ongoing impact of CMS programs on the Indian health system through analysis of, response to, and implementation of CMS regulations by Indian health providers.
- Study AI/AN demographic, enrollment, and utilization data and propose strategies to increase CMS data system capabilities to create more Indian specific reporting capacity.
- Provide ongoing study of CMS efforts to increase AI/AN knowledge of CMS programs and CMS responsiveness to Indian health system.
- Provide research support on the use and effectiveness of the CMS Tribal Consultation Policy. CMS requested that the NIHB submit an application which includes:
  1. Cover Letter.
  2. SF-424 Application for Federal Assistance.
  3. SF-424A Budget Information—Non-Construction Programs.
  4. A budget narrative (not to exceed three single spaced pages).
  5. Abstract of Project.
  6. A research project narrative that describes each of the four separate objectives (the entire narrative not to exceed 12 single space pages).
  7. SF-424B Assurances.
  8. Health Board Resolution.
  9. 501(c)(3) Non-Profit certification.
  10. Resumes of all key personnel.
  11. Position descriptions.

12. Disclosure of Lobbying Activities, if applicable.

13. Copy of approved indirect cost rate agreement, if applicable.

14. Documentation of current OMB A-133 required financial audit, if applicable.

Evaluation criteria for review of the application will be comprised of three principal areas:

a. Program information which includes current organizational capabilities and operations.

b. Program planning and evaluation which includes identification of measurable goals, products, personnel and workplanning.

c. Program reporting which includes organizational capabilities and qualifications and categorical budget and justification.

**Authority:** Section 1110 of the Social Security Act, codified at 42 U.S.C. 1310.

Dated: August 16, 2012.

**Daniel F. Kane,**

*Chief Grants Management Officer, Office of Acquisition and Grants Management, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-0755]

#### **Draft Compliance Policy Guide Sec. 690.150 on Labeling and Marketing of Nutritional Products Intended for Use To Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) entitled "Compliance Policy Guide Sec. 690.150 Labeling and Marketing of Nutritional Products Intended for Use to Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats." This draft CPG is intended to provide guidance to FDA staff and industry on how FDA intends to use its enforcement discretion with regard to the labeling and marketing of dog and cat food products that are labeled and/or marketed as intending to diagnose, cure, mitigate, treat, or prevent diseases and to provide nutrients in support of meeting the animal's total daily nutrient requirements.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft CPG before it begins work on the final version of the CPG, submit either electronic or written comments on the draft CPG by November 9, 2012.

**ADDRESSES:** Submit written requests for single copies of the draft CPG to the Director, Division of Compliance Policy, Office of Enforcement, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., rm. 4044, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-827-0482. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG. Submit electronic comments to <http://www.regulations.gov>.

Submit written comments on the draft CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** William J. Burkholder, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6865, [William.Burkholder@fda.hhs.gov](mailto:William.Burkholder@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft CPG entitled "Labeling and Marketing of Nutritional Products Intended for Use to Diagnose, Cure, Mitigate, Treat, or Prevent Disease in Dogs and Cats." The purpose of this CPG is to communicate FDA's strategy for enforcing the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) with respect to dog and cat food products that make labeling or marketing claims to diagnose, cure, mitigate, treat, or prevent disease. Since 1988, the Center for Veterinary Medicine (CVM) has observed an increase in the number of dog and cat food products making such claims that are sold with, or without, the direction of a licensed veterinarian. Because of this increase, and to help ensure animal safety, CVM is issuing this draft CPG to set out its current thinking with respect to factors it will consider before determining whether to take regulatory action against dog and cat food products intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.

FDA does not generally intend to recommend or initiate regulatory actions against dog and cat food products that are labeled and/or

marketed as intended for use to diagnose, cure, mitigate, treat, or prevent diseases and to provide nutrients in support of meeting the animal's total daily nutrient requirements when all the following factors are present. Specifically: (1) Manufacturers make the products available to the public only through licensed veterinarians or through retail or Internet sales to individuals purchasing the product under the direction of a veterinarian; (2) manufacturers do not market such products as alternatives to approved new animal drugs; (3) the manufacturer is registered under section 415 of the FD&C Act (21 U.S.C. 350(d)); (4) manufacturers comply with all food labeling requirements for such products (see 21 CFR part 501); (5) manufacturers do not include indications for a disease claim (e.g., obesity, renal failure) on the label of such products; (6) manufacturers limit distribution of material with any disease claims for such products only to veterinary professionals; (7) manufacturers secure electronic resources for the dissemination of labeling information and promotional materials such that they are available only to veterinary professionals; (8) manufacturers include only ingredients that are general regarded as safe (GRAS) ingredients, approved food additives, or feed ingredients defined in the 2012 *Official Publication* of the Association of American Feed Control Officials (AAFCO) for the intended uses in such products;<sup>1</sup> and (9) the label and labeling for such products are not false and misleading in other respects.<sup>2</sup>

##### **II. Significance of Guidance**

This level 1 draft CPG is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the

<sup>1</sup> Although food containing these unapproved food additives is adulterated within the meaning of section 402(a)(2)(c)(i), FDA is unlikely to initiate enforcement action solely on this basis if the food additive in question is included in the 2012 edition of the *Official Publication* of AAFCO. As part of its efforts to work with State partners, FDA has reviewed safety information related to many of these listed products, and those listed in the 2012 *Official Publication* generally do not fall within our current enforcement priorities.

<sup>2</sup> A therapeutic claim that is not scientifically substantiated would be considered false or misleading, thus making the product misbranded.